

PATENT COOPERATION TREATY

PCT

RECD 27 NOV 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 5885-WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK00/00300	International filing date (day/month/year) 02/06/2000	Priority date (day/month/year) 02/06/1999
International Patent Classification (IPC) or national classification and IPC C12N9/20		RECEIVED MAY 08 2001
Applicant NOVOZYMES A/S et al.		TECH CENTER 1600 2900

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 27/11/2000	Date of completion of this report 23.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Vollbach, S Telephone No. +49 89 2399 8715 

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International application No. PCT/DK00/00300

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-13 as originally filed

Claims, No.:

1-17 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

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(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-17
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-17
Industrial applicability (IA)	Yes:	Claims 1-17
	No:	Claims

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2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

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Re Item IV

Lack of unity of invention

see explanation under item V.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The modification of lipolytic enzymes by linking one or more hydrophobic groups to said enzyme is disclosed in several of the prior art documents cited in the search report (all documents categorized x cited in the search report e.g. Proceedings of the 20th European Peptide Symposium, 4-9 September 1998, meeting date 1988, 667-9, VAN BINSBERGEN JAN et al., Editors GUENTHER JUNG, ERNST BAYER, 'Peptides 1988', pages 667-668. XP002931955. D2: 'Transesterification of oil by fatty acid-modified lipase', 'MOTOTAKE MURAKAMI ET AL.', 'JAOCS', 70/6/00-00-1993, 571-574).

Therefore none of the generally drafted claims fulfils the requirements of Articles 33.2 PCT.

Should the applicant intend to file an amended set of claims which shall be suitable to overcome the objections above, the following additional considerations should be taken into account:

Especially in view of the prior art, a meaningful identification of the contribution over said art must be accompanied by a clear characterisation of the parent enzyme and the kind of modification. In the absence of precisely characterising said enzyme especially definitions as can be found in e.g. claim 2 are totally meaningless (Article 6 PCT).

In addition, the maintenance of various alternatives (either in one claim or in several independent claims) will most probably give rise to objections for lack of unity (again in view of the prior art) (Rules 13.1-13.3 PCT).

Moreover, any "modified lipolytic enzyme" to be maintained in the claims should be accompanied by experimental results in order to substantiate a possible inventive activity.

Re Item VIII

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Certain observations on the international application
see explanation under item V.